



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/475,822	06/07/1995	MARC ALIZON	3495.0010-24	4214

22852 7590 12/20/2002

FINNEGAN, HENDERSON, FARABOW, GARRETT &  
DUNNER LLP  
1300 I STREET, NW  
WASHINGTON, DC 20006

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/20/2002

34

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/475,822

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## **DETAILED ACTION**

### ***Double Patenting***

1. The double patenting rejections are withdrawn in view of the claim amendments in this case and the related cases.

### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires that when new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Here, two claims are numbered "41".

Misnumbered claim 41 been renumbered 42. Specifically, the second claim "41", drawn to the kit of claim 41, was renumbered 42.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

Art Unit: 1637

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 35, 37, 39, 41, 43 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 4000 and 9000 are presented below.

```
Query: 4010 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4069
          |||
Sbjct: 4197 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4256
pol      856 I P Y N P Q S Q G V V E S M N K E L K K
```

```
Query: 4070 ttataggacaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4129
          |||
Sbjct: 4257 ttataggccaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4316
```

Art Unit: 1637

pol 876 I I G Q V R D Q A E H L K T A V Q M A V

Query: 4130 tcatccacaatttttaaagaaaaannnnnnnnnnnnnnntacagtgcaggggaaagaatag 4189

|||||

Sbjct: 4317 tcatccacaatttttaaagaaaaggggggattgggggtacagtgcaggggaaagaatag 4376

pol 896 F I H N F K R K G G I G G Y S A G E R I

Query: 4190 tagacataatagcaacagacatacaaaactaaagaattacaaaaacaaattacaaaaattc 4249

|||||

Sbjct: 4377 tagacataatagcaacagacatacaaaactaaagaattacaaaaacaaattacaaaaattc 4436

pol 916 V D I I A T D I Q T K E L Q K Q I T K I

Query: 4250 aaaatthttcgggtttattacagggacagcagaaatccactttggaaaggaccagcaaagc 4309

|||||

Sbjct: 4437 aaaatthttcgggtttattacagggacagcagagatccactttggaaaggaccagcaaagc 4496

pol 936 Q N F R V Y Y R D S R D P L W K G P A K

Query: 4310 tcctctggaaaggtgaaggggcagtagtaatacaagataatagtgacataaaagtagtgc 4369

|||||

Sbjct: 4497 tcctctggaaaggtgaaggggcagtagtaatacaagataatagtgacataaaagtagtgc 4556

pol 956 L L W K G E G A V V I Q D N S D I K V V

Query: 4370 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4429

|||||

Sbjct: 4557 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4616

pol 976 P R R K A K I I R D Y G K Q M A G D D C

Query: 4430 tggcaagtagacaggatgaggattagaacatggaaaagtttagtaaaacacccatatgtat 4489

|||||

Sbjct: 4617 tggcaagtagacaggatgaggattagaacatggaaaagtttagtaaaacacccatatgtat 4676

pol 996 V A S R Q D E D ^^^

Query: 4490 gtttcagggaaagctaggggatggttttatagacatcactatgaaagccctcatccaaga 4549

|||||

Sbjct: 4677 gtttcagggaaagctaggggatggttttatagacatcactatgaaagccctcatccaaga 4736

Query: 4550 ataagttcagaagtacacatcccactaggggatgctagattggtaataacaacatattgg 4609

|||||

Sbjct: 4737 ataagttcagaagtacacatcccactaggggatgctagattggtaataacaacatattgg 4796

Query: 4610 ggtctgcatacaggagaaagagactggcatttgggtcagggagtctccatagaatggagg 4669

|||||

Sbjct: 4797 ggtctgcatacaggagaaagagactggcatttgggtcagggagtctccatagaatggagg 4856

Art Unit: 1637

Query: 4670 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4729  
|||||

Sbjct: 4857 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4916

Query: 4730 tactttgactgtttttcagactctgctataagaaaggccttattaggacacatagtttagc 4789  
|||||

Sbjct: 4917 tactttgactgtttttcagactctgctataagaaaggccttattaggacatatagtttagc 4976

Query: 4790 cctagggtgtgaatatcaagcaggacataacaaggtaggatctctacaatacttggcacta 4849  
|||||

Sbjct: 4977 cctagggtgtgaatatcaagcaggacataacaaggtaggatctctacaatacttggcacta 5036

Query: 4850 gcagcattaataacacccaaaaagataaagccacctttgcctagtgttacgaaactgaca 4909  
|||||

Sbjct: 5037 gcagcattaataacacccaaaaagataaagccacctttgcctagtgttacgaaactgaca 5096

Query: 4910 gaggatagatggaacaagccccagaagaccaagggccacagaggaggccacacaatgaat 4969  
|||||

Sbjct: 5097 gaggatagatggaacaagccccagaagaccaagggccacagaggaggccacacaatgaat 5156

Query: 4970 ggacactagagcttttagaggagcttaagaatgaagctgtagacattttcctaggattt 5029  
|||||

Sbjct: 5157 ggacactagagcttttagaggagcttaagaatgaanctgtagacattttcctaggattt 5216

Query: 5030 ggctccatggcttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5089  
|||||

Sbjct: 5217 ggctccatggcttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5276

Query: 5090 aagccataataagaattctgcaacaactgctgtttatccattttcagaattgggtgtcga 5149  
|||||

Sbjct: 5277 aagccataataagaattctgcaacaactgntgtttatcca-tttcagaattgggtgtcga 5335

Query: 5150 catagcagaataggcggttactcgacagaggagagcaagaaatggagccagtagatcctag 5209  
|||||

Sbjct: 5336 catagcagaataggcggttactcaacagaggagagcaagaaatggagccagtagatcctag 5395

Query: 5210 actagagccctggaagcatccaggaagtcagcctaaaactgcttgtaccaattgctattg 5269  
|||||

Sbjct: 5396 actaganccctggaagcatccaggaagtcagcctaaaactgcttgtaccacttnntattg 5455

Query: 5270 taaaaagtgttgctttcattgccaagtttgctttcataacaaaagccttaggcattctccta 5329  
|||||

Sbjct: 5456 taaaaagtgttgctttcattgccaagtttgctttcacacaaaagccttaggcattctccta 5515  
orfQ 1 C Q V C F T T K A L G I S Y

Art Unit: 1637

Query: 5330 tggcaggaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5389  
|||||

Sbjct: 5516 tggcannaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5575  
orfQ 15 G X K K R R Q R R R P P Q G S Q T H Q V

Query: 5390 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaatagcaatagtagc 5449  
|||||

Sbjct: 5576 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaatagcaatagcagc 5635  
orfQ 35 S L S K Q ^^^

Query: 5450 attagtagtagcaataataatagcaatagttgtgtggtccatagtaatcatagaatatag 5509  
|||||

Sbjct: 5636 attagtagtagcaataataatagcaatagttgtgtggtccatagtaatcatagaatatag 5695

Query: 5510 gaaaatattaagacaaagaaaaatagacaggttaattgatagactaatagaaagagcaga 5569  
|||||

Sbjct: 5696 gaaaatattaagacaaagaaaaatagacaggttaattgatagactaatagaaagagcaga 5755  
env 1 K E Q

Query: 5570 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggagat 5629  
|||||

Sbjct: 5756 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggaaat 5815  
env 4 K T V A M R V K E K Y Q H L W R W G W K

Query: 5630 ggggcaccatgctccttgggatgttgatgatctgtagtgtctacagaaaaattgtgggtca 5689  
|||||

Sbjct: 5816 ggggcaccatgctccttgggatattgatgatctgtagtgtctacagaaaaattgtgggtca 5875  
env 24 W G T M L L G I L M I C S A T E K L W V

Query: 5690 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5749  
|||||

Sbjct: 5876 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5935  
env 44 T V Y Y G V P V W K E A T T T L F C A S

Query: 5750 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtacca 5809  
|||||

Sbjct: 5936 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtacca 5995  
env 64 D A K A Y D T E V H N V W A T H A C V P

Query: 5810 cagaccccaaccacacaagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 5869  
|||||

Sbjct: 5996 cagaccccaaccacacaagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 6055  
env 84 T D P N P Q E V V L V N V T E N F N M W

Art Unit: 1637

Query: 5870 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 5929  
|||||  
Sbjct: 6056 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 6115  
env 104 K N D M V E Q M H E D I I S L W D Q S L

Query: 5930 agccatgtgtaaaattaaccccactctgtgttagtttaaagtgcactgatttgaagaatg 5989  
|||||  
Sbjct: 6116 agccatgtgtaaaattaaccccactctgtgttagtttaaagtgcactgatttggggaatg 6175  
env 124 K P C V K L T P L C V S L K C T D L G N

Query: 5994 taataccaatagtagtagcgaggagaatgataatggagaaaggagagataaaaaactgctc 6053  
|||||  
Sbjct: 6195 taataccaatagtagtagcgaggagaatgatgatggagaaaggagagataaaaaactgctc 6254  
env 151 N T N S S S G E M M M E K G E I K N C S

Query: 6054 tttcaatatcagcacaagcataagaggtaagggtgcagaaagaatatgcannnnnnnataa 6113  
|||||  
Sbjct: 6255 tttcaatatcagcacaagcataagaggtaagggtgcagaaagaatatgcatttttttataa 6314  
env 171 F N I S T S I R G K V Q K E Y A F F Y K

Query: 6114 acttgatataataccaatagataatgatactaccagctatacgttgacaagttgtaacac 6173  
|||||  
Sbjct: 6315 acttgatataataccaatagataatgatactaccagctatacgttgacaagttgtaacac 6374  
env 191 L D I I P I D N D T T S Y T L T S C N T

Query: 6174 ctcagtcattacacaggcctgtccaaagggtatcctttgagccaattcccatacattattg 6233  
|||||  
Sbjct: 6375 ctcagtcattacacaggcctgtccaaagggtatcctttgagccaattcccatacattattg 6434  
env 211 S V I T Q A C P K V S F E P I P I H Y C

Query: 6234 tgccccggctgggttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6293  
|||||  
Sbjct: 6435 tgccccggctgggttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6494  
env 231 A P A G F A I L K C N N K T F N G T G P

Query: 6294 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6353  
|||||  
Sbjct: 6495 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6554  
env 251 C T N V S T V Q C T H G I R P V V S T Q

Query: 6354 actgctgttaaatggcagctctggcagaagaagaggtagtaattagatctgccaatttcac 6413  
|||||  
Sbjct: 6555 actgctgttgaatggcagctctagcagaagaagaggtagtaattagatctgccaatttcac 6614  
env 271 L L L N G S L A E E E V V I R S A N F T



Art Unit: 1637

Query: 6414 agacaatgctaaaaccataatagtagtacagctgaaccaatctgtagaaattaattgtacaag 6473

|||||

Sbjct: 6615 agacaatgctaaaaccataatagtagtacagctgaaccaatctgtagaaattaattgtacaag 6674

env 291 D N A K T I I V Q L N Q S V E I N C T R

Query: 6474 acccaacaacaataacaagaaaaagtatccgtatccagagaggaccagggagagcatttgt 6533

|||||

Sbjct: 6675 acccaacaacaataacaagaaaaagtatccgtatccagaggggaccagggagagcatttgt 6734

env 311 P N N N T R K S I R I Q R G P G R A F V

Query: 6534 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6593

|||||

Sbjct: 6735 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6794

env 331 T I G K I G N M R Q A H C N I S R A K W

Query: 6594 gaataacacttttaaacagatagatagcaaattaagagaacaatttggaaataataaaaac 6653

|||||

Sbjct: 6795 gaatgccacttttaaacagatagctagcaaattaagagaacaatttggaaataataaaaac 6854

env 351 N A T L K Q I A S K L R E Q F G N N K T

Query: 6654 aataatctttaagcagtcctcaggaggggacccagaaattgtaacgcacagttttaattg 6713

|||||

Sbjct: 6855 aataatctttaagcaatcctcaggaggggacccagaaattgtaacgcacagttttaattg 6914

env 371 I I F K Q S S G G D P E I V T H S F N C

Query: 6714 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttgggttaatag 6773

|||||

Sbjct: 6915 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttgggttaatag 6974

env 391 G G E F F Y C N S T Q L F N S T W F N S

Query: 6774 tacttggagtactaaaggggtcaaataacactgaaggaagtgaacacaatcacctcccatg 6833

|||||

Sbjct: 6975 tacttggagtactgaaggggtcaaataacactgaaggaagtgaacacaatcacactcccatg 7034

env 411 T W S T E G S N N T E G S D T I T L P C

Query: 6834 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 6893

|||||

Sbjct: 7035 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 7094

env 431 R I K Q F I N M W Q E V G K A M Y A P P

Query: 6894 catcagtgagacaaattagatgttcacaaatattacagggctgctattaacaagagatgg 6953

|||||

Sbjct: 7095 catcagcgagacaaattagatgttcacaaatattacagggctgctattaacaagagatgg 7154

env 451 I S G Q I R C S S N I T G L L L T R D G

Art Unit: 1637

Query: 6954 ttgtaatagcaacaatgagtcgagatcttcagacctggaggaggagatatgagggacaa 7013

Sbjct: 7155 ttgtaataacaacaatgggtccgagatcttcagacctggaggaggagatatgagggacaa 7214  
env 471 G N N N N G S E I F R P G G G D M R D N

Query: 7014 ttggagaagtgaattatataaaatataaaagtagtaaaaaattgaaccattaggagtagcacc 7073

Sbjct: 7215 ttggagaagtgaattatataaaatataaaagtagtaaaaaattgaaccattaggagtagcacc 7274  
env 491 W R S E L Y K Y K V V K I E P L G V A P

Query: 7074 caccaaggcaaagagaagagtgggtgcagagagaaaaaagagcagtgggaataggagcttt 7133

Sbjct: 7275 caccaaggcaaagagaagagtgggtgcagagagaaaaaagagcagtgggaataggagcttt 7334  
env 511 T K A K R R V V Q R E K R A V G I G A L

Query: 7134 gttccttgggttcttggggagcagcaggaagcactatgggcgacgctcaatgacgctgac 7193

Sbjct: 7335 gttccttgggttcttggggagcagcaggaagcactatgggcgacgctcaatgacgctgac 7394  
env 531 F L G F L G A A G S T M G A R S M T L T

Query: 7194 ggtacaggccagacaattattgtctggtatagtgacgagcagaacaatttgctgagggc 7253

Sbjct: 7395 ggtacaggccagacaattattgtctggtatagtgacgagcagaacaatttgctgagggc 7454  
env 551 V Q A R Q L L S G I V Q Q Q N N L L R A

Query: 7254 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7313

Sbjct: 7455 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7514  
env 571 I E A Q Q H L L Q L T V W G I K Q L Q A

Query: 7314 aagaatcctggctgttggaagatacctaaggatcaacagctcctggggatttgggggttg 7373

Sbjct: 7515 aagaatcctggctgttggaagatacctaaggatcaacagctcctgggnatttgggggttg 7574  
env 591 R I L A V E R Y L K D Q Q L L G I W G C

Query: 7374 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagtggagtaataaatc 7433

Sbjct: 7575 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagtggagtaataaatc 7634  
env 611 S G K L I C T T A V P W N A S W S N K S

Query: 7434 tctggaacagatttgggaataacatgacctggatggagtgggacagagaaattaacaatta 7493

Sbjct: 7635 tctggaacagatttgggaataacatgacctggatggagtgggacagagaaattaacaatta 7694  
env 631 L E Q I W N N M T W M E W D R E I N N Y

Art Unit: 1637

Query: 7494 cacaagcttaatacactccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7553  
|||||  
Sbjct: 7695 cacaagcttaatacattccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7754  
env 651 T S L I H S L I E E S Q N Q Q E K N E Q

Query: 7554 agaattattggaattagataaatgggcaagtttggtgaattggtttaacataacaaattg 7613  
|||||  
Sbjct: 7755 agaattattggaattagataaatgggcaagtttggtgaattggtttaacataacaaattg 7814  
env 671 E L L E L D K W A S L W N W F N I T N W

Query: 7614 gctgtggtatataaaaattattcataatgatagtaggaggcttggtagggtttaagaatagt 7673  
|||||  
Sbjct: 7815 gctgtggtatataaaaattattcataatgatagtaggaggcttggtagggtttaagaatagt 7874  
env 691 L W Y I K I F I M I V G G L V G L R I V

Query: 7674 ttttgctgtactttctgtagtgaatagagtttaggcagggatattcaccattatcgtttca 7733  
|||||  
Sbjct: 7875 ttttgctgtactttctatagtgaatagagtttaggcagggatattcaccattatcgtttca 7934  
env 711 F A V L S I V N R V R Q G Y S P L S F Q

Query: 7734 gaccacaccccaatcccgaggggacccgacaggcccggaaggaatagaagaagaaggtgg 7793  
|||||  
Sbjct: 7935 gaccacaccccaaccccgaggggacccgacaggcccggaaggaatagaagaagaaggtgg 7994  
env 731 T H L P T P R G P D R P E G I E E E G G

Query: 7794 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 7853  
|||||  
Sbjct: 7995 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 8054  
env 751 E R D R D R S I R L V N G S L A L I W D

Query: 7854 cgatctgaggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 7913  
|||||  
Sbjct: 8055 cgatctgaggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 8114  
env 771 D L R S L C L F S Y H R L R D L L L I V

Query: 7914 aacgaggattgtggaacttctgggacgcagggggtgggaagccctcaaattattggtggaa 7973  
|||||  
Sbjct: 8115 aacgaggattgtggaacttctgggacgcagggggtgggaagccctcaaattattggtggaa 8174  
env 791 T R I V E L L G R R G W E A L K Y W W N

Query: 7974 tctcctacagtattggagtcaggagctaaagaatagtgtgttagcttgctcaatgccac 8033  
|||||  
Sbjct: 8175 tctcctacagtattggagtcaggaaactaaagaatagtgtgttagcttgctcaatgccac 8234  
env 811 L L Q Y W S Q E L K N S A V S L L N A T

Art Unit: 1637

Query: 8034 agctatagcagtagctgaggggacagatagggttatagaagtagtacaaggagcttatag 8093  
||| |||||

Sbjct: 8235 agccatagcagtagctgagggnacagatagggttatagaagtagtacaaggagctttag 8294  
env 831 A I A V A E G T D R V I E V V Q G A C R

Query: 8094 agctattcgccacatacctagaagaataagacagggcttggaaaggattttgctataaga 8153  
|||||

Sbjct: 8295 agctattcgccacatacctagaagaataagacagggcttggaaaggattttgctataaga 8354  
orfF 1 D R A W K G F C Y K  
env 851 A I R H I P R R I R Q G L E R I L L ^^

Query: 8154 tgggtggcaagtgggtcaaaaagtagtgtggttggatggcctgctgtaagggaaagaatga 8213  
|||||

Sbjct: 8355 tgggtggcaagtgggtcaaaaagtagtgtggttggatggcctactgtaagggaaagaatga 8414  
orfF 11 M G G K W S K S S V V G W P T V R E R M

Query: 8214 gacgagctgagccagcagcagatgggggtgggagcagcatctcgagacctagaaaaacatg 8273  
|||||

Sbjct: 8415 gacgagctgagccagcagcagatgggggtgggagcagcatctcgagacctgaaaaacatg 8474  
orfF 31 R R A E P A A D G V G A A S R D L E K H

Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333  
|||||

Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcac 8534  
orfF 51 G A I T S S N T A A T N A A C A W L E A

Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393  
|||||

Sbjct: 8535 aagaggaggaggaggtgggttttccactcacacctcaggtacctttaagaccaatgactt 8594  
orfF 71 Q E E E E V G F P L T P Q V P L R P M T

Query: 8394 acaaggcagctgtagatcttagccacttttttaaagaaaaggggggactggaagggctaa 8453  
|||||

Sbjct: 8595 acaaggcagctgtagatcttagccacttttttaaagaaaaggggggactggaagggctaa 8654  
orfF 91 Y K A A V D L S H F L K E K G G L E G L

Query: 8454 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513  
|||||

Sbjct: 8655 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714  
orfF 111 I H S Q R R Q D I L D L W I Y H T Q G Y

Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573  
|||||

Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774

Art Unit: 1637

orfF 131 F P D W Q N Y T P G P G V R Y P L T F G

Query: 8574 ggtgctacaagctagtagtaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633

|||||

Sbjct: 8775 ggtgctacaagctagtagtaccagttgagccagataaggtagaagaggccaataaaggagaga 8834

orfF 151 W C Y K L V P V E P D K V E E A N K G E

Query: 8634 acaccagcttggttacaccctgtgagcctgcatggaatggatgacccggagagagaagtgt 8693

|||||

Sbjct: 8835 acaccagcttggttacaccctgtgagcctgcatggaatggatgacccgtgagagagaagtgt 8894

orfF 171 N T S L L H P V S L H G M D D P E R E V

Query: 8694 tagagtggaggtttgacagccgcctagcatttcacatggcccgagagctgcatccgg 8753

|||||

Sbjct: 8895 tagagtggaggtttgacagccgcctagcatttcacatggcccgagagctgcatccgg 8954

orfF 191 L E W R F D S R L A F H H V A R E L H P

Query: 8754 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 8813

|||||

Sbjct: 8955 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 9014

orfF 211 E Y F K N C ^^^

Query: 8814 cagggaggcgtggcctggcgaggactggggagtggcgagccctcagatcctgcatataag 8873

|||||

Sbjct: 9015 cagggaggcgtggcctggcgaggactggggagtggcgagccctcagatgctgcatataa 9074

Query: 8874 cagctgctttttgcctgtactgggtctctctggttagaccagatctgagcctgggagctc 8933

|||||

Sbjct: 9075 cagctgctttttgcctgtactgggtctctctggttagaccagatttgagcctgggagctc 9134

Score = 2796 bits (1454), Expect = 0.0

Identities = 1477/1489 (99%)

Strand = Plus / Plus

It is noted that with regard to, for example, the sequence region between nucleotides 4487 and 5086 claimed in claim 11, there are two nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were

Art Unit: 1637

likely significantly higher. In the 599 nucleotide sequence which is the first sequence of claim 1, two errors would represent approximately a 0.3% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

With regard to the kit claims, it is noted that the preamble phrase "a kit" imposes no structural requirements upon the product claims.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 1637

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claims 35, 37, 39, 41, 43 and 45 as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claims 35, 37, 39, 41, 43 and 45 as discussed above, including detection of HIV-1 using nucleic acid probes by dot blotting.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Chang because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White to detect HIV as taught by Chang since White says that the method is

Art Unit: 1637

broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

***Response to Arguments***

7. Applicant's arguments filed November 18, 2002 have been fully considered but they are not persuasive.

Applicant argues that a comparison of the sequences of Chang and the present case show that Chang has stop codons which would prevent expression of the ORFs. This argument is not found persuasive for several reasons.

First, it is not simply the sequence which Chang teaches, but the specific DNA entity, the composition, which was in the lab. Because of the issue of sequencing error, addressed in the rejection itself, it is unclear whether these differences between the sequences identified by Applicant represent real differences or simply sequencing error. If the differences are real, as evidenced by a declaration (which is expressly invited), then applicant's argument would be persuasive. However, given the high probability of sequencing errors as discussed above, combined with the knowledge that due to contamination, the virus strain of Chang was the same virus strain as that used by Applicant, the rejections are maintained.

Second, since the claims are comprising, an diagnostic vector which comprises the entirety of the HIV genome would inherently comprise each and every ORF, including those claimed. Since such a vector is within the teaching of Chang, this clearly anticipates the current claims.



Third, to the extent that the argument relies upon the fact that Chang did not correctly identify these open reading frames due to the presence of stop codons, this argument is not persuasive because formation of random fragments as taught by Chang will create the vectors irrespective of whether Chang was aware of the open reading frames or not.

Fourth, to the extent that the argument relies upon actual sequence differences which create different open reading frames, no evidence is on record showing that the sequences are, in fact, different. A declaration which evidenced such a difference in sequence, which directly corresponded to a claim, would be valuable in this application and applicant is expressly invited to provide such a declaration. Currently, there is no evidence which rebuts the position that any differences are the result of sequencing error.

As a final point, it is noted that in this case, there is better evidence than is ordinarily available that the strains sequenced by the two different groups are, in fact, the same since it is clear that the LAI strain is common to both of these applications.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


Art Unit: 1637

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

December 19, 2002